K032079

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TORNIER

Implants Chirurgicaux

510(k) Summary of Safety and Effectiveness information
HLS NOETOS System – Revision prosthesis

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name: ***HLS NOETOS System***
Common name: Total anatomical knee prosthesis
Classification name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained

2) Submitter

Tornier S.A.
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier S.A.
Mrs Mireille Lémery
Regulatory affairs & Quality Engineer
ZIRST - 161, rue Lavoisier
38330 Montbonnot - France
Tel: 00 33 4 76 61 38 98
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e-mail : mireille.lemery@tornier.fr

4) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: 87JWH
Sec. 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

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S.A. au capital de 1 800 000 F
SIRET : 070 501 275 000 13
R.C.S. : B 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : B.P. 11 - rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

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5) Equivalent / Predicate device

- PFC Modular Total Knee System, DePuy (K984158),
- NEX-GEN Complete Knee Solution Legacy Constrained Condylar Knee L-CCK, Zimmer (K963148)
- HLS Noetos System, Tornier (K013906).

6) Device description

The usual goal of total knee replacement is to restore the knee joint to its best working condition and to reduce or eliminate pain. The *HLS NOETOS System* is intended to accomplish these goals. The *HLS NOETOS System* is intended for use as a total knee replacement system sacrificing the cruciate ligaments. The *HLS NOETOS System* provides the flexibility needed to adapt the implant and the therapeutic solution to the patients need. All the type of implants have been designed with the same objectives:

- to restore the joint line both in flexion and in extension without altering the patellar height,
- to restore the articular morphology and to preserve bone stock.

The design of the implant, particularly the tibial one, guarantees the antero-posterior stability, by a third femoral condyle that engages a specific tibial bearing area during flexion.

The *HLS NOETOS System – Revision prosthesis* consists of the association of three components: a femoral component, a tibial tray associated with a polyethylene bearing and a patellar implant. The patella can be preserved if it is in good state or resurfaced by the patellar implant. Femoral and tibial augments as well as femoral and tibial extension stems can be added in order to compensate for bone loss.

7) Materials

The femoral part is manufactured from Cobalt-Chromium alloy according to ISO standard 5832-4. The articulating surface, in contact with the bearing component, is mirror polished and the finished aspect of the part in contact with the bone is fine shotblasted. The tibial tray is also made from Cobalt-Chromium alloy according to ISO standard 5832-4. The finished aspect is fine shotblasted. The femoral and tibial spacers, the femoral stem adaptor and the sleeve for femoral stem adaptor are also made from Cobalt-Chromium alloy according to ISO standard 5832-7 or ISO standard 5832-12.

8) Indications

This device is indicated for use as a total knee replacement for the relief of pain and significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis. This device is also indicated for the revision of knee prosthesis.

The *HLS NOETOS Revision prosthesis* is intended for cemented use only.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Mrs. Mireille Lémery
Regulatory Affairs and Quality Engineer
Tornier, S.A.
ZIRST – 161, rue Lavoisier
38330 Montbonnot
France

Re: K032079
Trade/Device Name: HLS NOETOS System – Revision prosthesis
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: June 19, 2003
Received: July 7, 2003

Dear Mrs. Lémery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032079

Device name: ***HLS NOETOS System – Revision prosthesis***

Indication for use:

This device is indicated for use as a total knee replacement for the relief of pain and significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis. This device is also indicated for the revision of knee prosthesis.

The HLS NOETOS Revision prosthesis is intended for cemented use only.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032079

Prescription use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)